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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,079	10/22/2003	Luc Mercken	FRAV2002/0030 US NP	2372
5487 7590 04/03/2007 ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER KOLKER, DANIEL E	
			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/03/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/691,079	MERCKEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7 and 9-14 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The remarks and amendments filed 9 January 2007 have been entered. Claim 8 has been canceled; claims 1 – 7 and 9 – 14 are pending.

### ***Election/Restrictions***

2. Claims 2 – 5 and 10 – 14 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 April 2006.

3. This application contains claims 2 – 5 and 10 – 14 drawn to an invention nonelected with traverse in the reply filed on 13 April 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

4. Claims 1, 6 – 7, and 9 are under examination.

### ***Withdrawn Rejections and Objections***

5. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejections under 35 USC 101 are withdrawn in light of the amendments. The claims now encompass only statutory subject matter.

B. The rejection under 35 USC 112, first paragraph is withdrawn in light of the amendments. The claims are now limited to subject matter which is reasonably enabled by the disclosure.

C. The rejection of claim 1 under 35 USC 102(b) over Maly is withdrawn. The amendments to claim 1 have incorporated subject matter from original claim 8, which was not anticipated by Maly.

D. The rejections under 35 USC 102 and 103 over Tang are withdrawn in light of the amendments. Tang does not teach measuring phosphorylation, now recited in independent claim 1, nor does Tang teach identifying compounds as therapeutic compounds for Alzheimer's disease, as recited in claim 1.

***Rejections and Objections Necessitated by Amendment***

***Claim Objections***

6. Claims 6 – 7 and 9 are objected to because of the following informalities: They begin with the term “According to Claim 1”, which is awkward. To reflect more conventional claim language, it is recommended that applicant consider amending the claims to recite “The method according to claim 1”, or some similar wording.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6 – 7, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “said Src protein” in steps (a) and (c). There is no longer sufficient antecedent basis for this limitation in the claim, as the language “a Src protein” which had been present in the preamble has been canceled by amendment.

Furthermore, claim 1 is indefinite because it does not specify whether compounds to be identified are those which increase, decrease, or fail to change phosphorylation activity of Src protein. The specification and originally-filed claims indicate that inhibitors of Src protein would be expected to be potential therapeutics for Alzheimer’s disease. However claim 1, as currently written, only requires the artisan to measure the phosphorylation activity of Src, and then to identify “said candidate compound as the therapeutic”. There is no requirement that the candidate compound be able to increase or decrease Src phosphorylation activity. Thus the claimed methods are ambiguous, because the claims do not direct the skilled artisan to identify any particular candidate compounds as therapeutics. The claims are confusing because the skilled artisan could not determine whether those compounds which increase phosphorylation activity should be identified as therapeutics, or whether those compounds which decrease phosphorylation activity should be identified as therapeutics, or whether all compounds are therapeutics even if they do not change phosphorylation activity.

Claims 6 – 7 and 9 are rejected because they depend from claim 1 and fail to remedy these indefinite features of the claim.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson (2002. Journal of Neuroscience 22(1):10-20, cited on IDS filed 15 October 2004).

Williamson teaches providing rat cells which express Src protein and contacting the cells with candidate agents including PP2. See Williamson, p. 11, "Primary cortical neuronal cultures" and "Cell treatments". Williamson also teaches measuring the degree of tyrosine phosphorylation before and after addition of PP2; see p. 14, particularly Figure 5 and second column, section entitled "Src family...". As Src is a tyrosine kinase (i.e. it phosphorylates tyrosine residues on other proteins), and the reference teaches measuring tyrosine phosphorylation after addition of PP2, which is identified as a Src inhibitor, the reference teaches the step of "measuring the phosphorylation activity of said Src protein in response to said candidate compound". Finally, as the reference teaches that addition of A-beta peptide increases tyrosine phosphorylation and that such increase is associated with the cell death seen in Alzheimer's disease (see p. 10, first paragraph) and PP2 inhibits this phosphorylation, the reference fairly teaches the "identifying" step recited in claim 1. Note particularly Williamson's Figure 5D and the accompanying legend, which indicates that addition of A-beta rapidly increases tyrosine phosphorylation (compare lanes 1 and 2), and that this is decreased upon addition of PP2 (lane 3). Thus the reference anticipates every limitation of claim 1. As the reference teaches the use of primary neurons, it anticipates claim 9 as well.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6 – 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson (2002. Journal of Neuroscience 22(1):10-20) in view of UniProt accession number A43610 (sequence updated 16 June 2000).

The reasons why claims 1 and 9 are anticipated by Williamson are set forth in the previous rejection. However, the reference teaches rat Src, and does not teach mouse Src as recited in claim 6 or the protein of SEQ ID NO:3, as recited in claim 7.

Uniprot A43610 teaches a protein sequence. The sequence is identified as mouse Src protein, derived from neurons and therefore is on point to claim 6. The enclosed alignment shows that A43610 is 100% identical to applicant's SEQ ID NO:3, and therefore is on point to claim 7. However A43610 does not teach the method recited in claim 1.

It would have been obvious to one of ordinary skill in the art to use the mouse Src protein (i.e., SEQ ID NO:3) of A43610 in the method of claims 1 and 9, with a reasonable expectation of success. The motivation to do so would be to use mice as opposed to rats. Mice are smaller, require less cage space, eat less food, and thus are less costly to maintain. Thus performing the assay with mouse tissue as opposed to rat tissue would allow the artisan of ordinary skill to save money. It would be reasonable to expect success, as rats and mice have similar physiology, and are both rodents. Thus the artisan of ordinary skill would reasonably expect that the findings reported by Williamson would extend to mice as well.

### ***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.  
March 28, 2007



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER